

A Biolized, Compact, Low Noise, High Performance Implantable Electromechanical Ventricular Assist System

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An implantable electromechanical ventricular assist system (VAS) intended for permanent human use was developed. It consisted of a conically shaped pumping chamber, a polyolefin (Hexsyn) rubber diaphragm attached to a pusher-plate, and a compact actuator with a direct current brushless motor and a planetary rollerscrew. The outer diameter was 97 mm, and the total thickness was 70 mm. This design was chosen to give a stroke volume of 63 ml. The device weighs 620 g, with a total volume of 360 ml. The pump can provide 8 L/min flow against 120 mmHg afterload with a preload of 10 mmHg. The inner surface of the device, including the pumping chamber and diaphragm, was made biocompatible with a dry gelatin coating. To date, two subacute (2 and 6 day) calf studies have been conducted. The pump showed reasonable anatomic fit inside the left thorax, and the entire system functioned satisfactorily in both the fill-empty mode using the Hall effect sensor signals and the conventional fixed rate mode. There were no thromboembolic complications despite no anticoagulation therapy. The system now is being endurance tested > 10 weeks (9 million cycles). This VAS is compact, low noise, easy to control, and has excellent biocompatibility. *ASAIO Transactions* 1991; 37: M249-M251.

The implantable ventricular assist system (VAS) must be compact and light weight, and have high performance, high efficiency, reliable control, and excellent biocompatibility. It must be capable of supporting full cardiac output and anatomically and physiologically suitable for human use.¹ To meet these criteria, a prototype, compact electromechanical VAS was designed. This paper describes the design and *in vitro* and initial *in vivo* studies of the prototype VAS.

Materials and Methods

Blood Pump System

The prototype device consisted of a conically shaped epoxy pump housing, a conically shaped Hexsyn rubber dia-

phragm attached pusher-plate, and an actuator housing for a direct current brushless motor and planetary roller screw. The diaphragm was compressed between the pump and motor housings (Figure 1). The outer diameter of the pump was 97 mm, with a thickness of 32 mm. The total thickness of the assembled device was 70 mm. The design stroke volume was 63 ml, with the displacement of the pusher-plate 0.5 inch. The weight of the assembled pump was 620 g, and the overall volume was 360 ml. The inlet and outlet ports with 24 mm inner diameter were designed symmetrically. They were curved to guide the flow along the periphery of the housing to prevent the incoming flow from directly hitting the conically shaped diaphragm. The rotating unit, consisting of the rotor and rollerscrew nut assembly, was supported by a couple of bearings fixed in the motor housing. As the rotating unit turned, the rotational force of the motor was converted to the rectilinear motion of the rollerscrew through a square shaft attached to the back plate, which was guided inside the square hole of the screw. To control speed and direction of the motor rotation, two Hall effect sensors were incorporated. One was a rollerscrew position sensor used to reverse the direction of the motor rotation. The other was a pusher-plate position sensor used to detect the filling of the pump.

As a blood contacting surface, 5% glutaraldehyde cross-linked dry gelatin was coated on the textured pumping chamber and Hexsyn rubber diaphragm; 21 mm bovine pericardial valves were used as the inflow and outflow valves.

The compliance port was vented to the atmosphere in this design.

Control System

This control unit was capable of both the fill-empty (F/E) and fixed rate (FR) modes. The F/E operation was achieved by sensing the displacement of the pusher-plate. When the pump finished its ejection, the rollerscrew was retracted quickly to the end-diastolic position and waited for complete filling of the pump. Thus, when the pump filling became faster with increases in the filling pressure, the pump rate increased, resulting in augmentation of the output. The motor power, end-systolic, and end-diastolic position of the pusher-plate and rollerscrew could be adjusted to obtain optimum conditions. In the FR mode, the internal pulse generator was used to set the pump rate, and the pump usually was operated in the fill-limited mode.

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Pump Performance Study

In vitro performance mapping was done using a mock circulation, consisting of an inflow chamber, compliance chamber, back pressure regulator, and flow meter. The pump, with no inflow conduit, was immersed in the water to evaluate intrinsic pump sensitivity. Initially, the complete filling time was measured at different preloads. Then, pump outputs were obtained in both the FR and F/E modes as a function of the filling pressure for the various afterloads.

In Vivo Study

This VAS was implanted in two calves as subacute *in vivo* experiments of system readiness. The blood was drained from the apex of the left ventricle using a specially designed inflow conduit, consisting of a right angled rigid tip and a coated, impervious, semirigid Dacron graft; it then was returned to the thoracic descending aorta. No anticoagulation therapy was used except during surgery.

Results

The ventricle was filled passively in 280 msec with a preload of 10 mmHg. This pump could provide an 8 L/min output against a mean afterload of 120 mmHg, with a filling pressure of 10 mmHg (Figure 2). The maximum flow was approximately 10 L/min when the pump rate was operated at 170 bpm in the F/E mode. To provide 5–8 L/min flow against 120 mmHg, the required input power of the system was 8–11 watts. The net efficiency, computed as the ratio of the pump output power divided by the electrical input power, ranged from 20% to 15% without a transcutaneous transformer system. The endurance test currently is on-going and exceeds 10 weeks (9 million cycles).

To date, two subacute *in vivo* experiments were conducted. One lasted 2 days and the other, 6. The VAS was

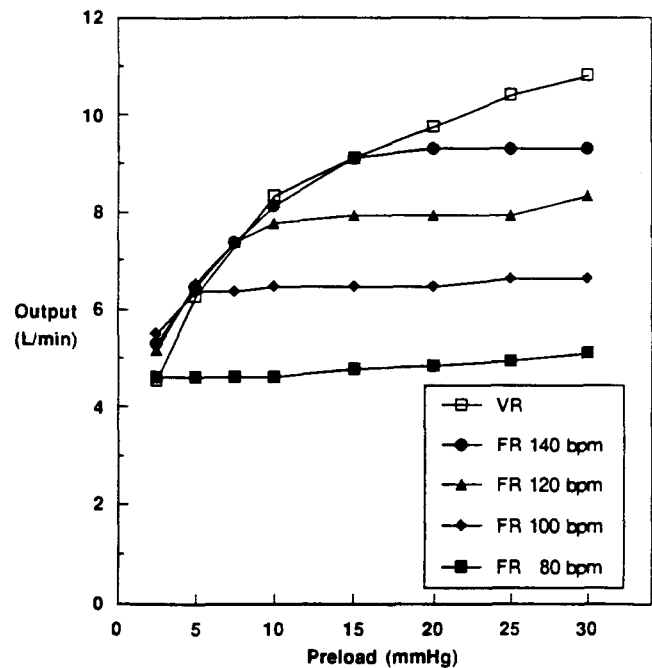


Figure 2. Performance mapping in both the fixed rate (FR) and the fill/empty, or variable rate (VR) modes.

placed in the preperitoneal space in the first case and in the left chest cavity in the second case. The system was operated most of the time in the F/E mode, and it functioned satisfactorily in both the F/E and FR modes. In the F/E mode, this system was able to follow the natural heart beat synchronously up to 140 bpm with the pump being completely filled passively. Although no anticoagulation therapy was used except during cannulation, there were no thromboembolic complications. During these studies, mechanical noise was minimal. This system showed reasonable anatomic fit in the thoracic cavities of these animals.

Discussion

The newly developed VAS: 1) is compact and light weight, with low noise, 2) has high performance, efficiency, and longevity, 3) is reliable to control and monitor, and 4) has excellent biocompatibility. The implantable VASs available today are somewhat large and difficult to implant.² We emphasized the significance of anatomic fit to minimize the overall volume to about 360 ml; this is the smallest of all existing VASs. The high performance, efficiency (15–20%), and longevity were achieved by the combination of a pusher-plate pump with a Hexsyn rubber diaphragm and a rollerscrew. The theoretic longevity of the rollerscrew is so long (the 10% probability of failure is over 1,000 years) that it will not limit the durability of the entire system. The flex life of Hexsyn rubber is over 350 million cycles, approximately 6–7 years. At present, Hexsyn rubber shows the best flex life when used as an artificial heart diaphragm. Reliable control and monitoring of pumping are achieved by a Hall effect sensor.

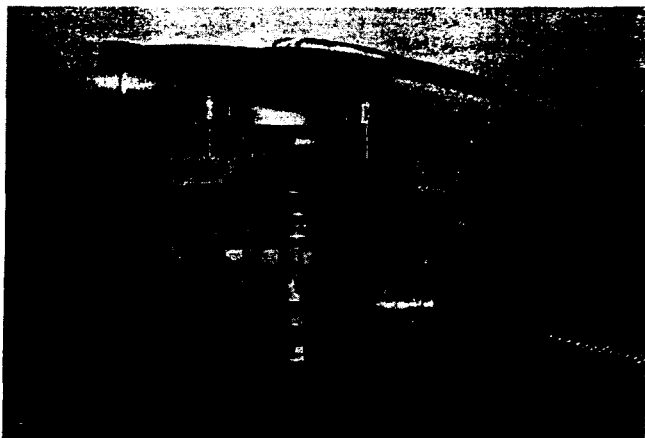


Figure 1. Components of the prototype implantable electromechanical VAS.

The F/E mode implemented using the pusher-plate Hall effect position signal is effective in providing both pressure and volume unloading of the left ventricle. In addition, pump rate, stroke volume, and flow rate can be computed accurately from the Hall sensor position signal. The Hall sensor signal also is used to transfer the control mode from F/E to FR automatically, in case F/E mode failure develops. As blood contacting surfaces, 5% glutaraldehyde cross-linked gels (so-called wet gelatins) have shown excellent biocompatibility. However, wet gelatin requires tedious sterilization by formaldehyde, and long-term storage is a problem. Studies by others³ showed that the dry gelatin process provides a stable film coating and eliminates the sterilization and storage problems of wet gelatin.

In conclusion, our implantable electromechanical VAS is compact, low weight, and capable of supporting the full cardiac output of the patient. The desirable features of low volume, low noise, high performance, and long-term durability make it suitable for permanent support of the end-stage cardiac patient.

References

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